



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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Food and Drug Administration
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Stoneham, Massachusetts 02180
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August 6, 1998

NWE-19-98W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Martin Howard, President
Willows General Store, Inc.
70 Fairfield Beach Road
Westport, CT 06880

Dear Mr. Howard:

This letter is in reference to the promotion, marketing, and distribution of products with disease claims. Examples of these products and their claims are:

- o "Maximum Strength Prostaïd": "If your prostate is starting to give you trouble, you're not alone. 75% of all men over the age of 50 have enlargement of the prostate gland. The problems you can experience can be frequent, difficult, painful or weak urination"; "Our 100% natural treatment "MSP" works much better than surgery or drugs"; "Saw palmetto extract is twice as effective for relieving BPH symptoms as the most common drug"; "80% of BPH patients show **"significant improvement"** in their condition after taking *Pygeum africanum* for 30 days. In France, doctors prescribed *Pygeum africanum* 90% of the time to treat BPH patients"; "Do you ... get up at night to urinate? often have sudden urges to urinate? have a weak urine stream? frequently need to urinate? have the sensation that you have not emptied your bladder completely after urinating? stop and start again several times when you urinate? have to push or strain to begin to urinate?";
- o "Prost-Aid NS": "Medical treatment has become available for the treatment of benign hypertrophy of the prostate. Drug derived from plants are widely used for this purpose in Europe and the U.S."; "200 patients with symptomatic BPH were treated with either Beta-Sitosterol or a placebo. After a six-month period, the Beta-Sitosterol treated group showed a significant decrease in residual urinary

- volume retained, an increase in peak urine flow, and an improvement of 7.4 points in IPSS (International Prostate Symptom Score) which is used world-wide to measure basic prostate health."; "Significant improvement in symptoms and urinary flow parameters show the effectiveness of Beta-Sitosterol in the treatment of BPH."; "the findings of these studies support the effectiveness of the 100% natural (Beta-Sitosterol) ingredient which is found in Prost-Aid NS."; "A medically proven 100% natural remedy.";
- o "Extra Strength ProstaAid": "Prostate problems affect men physically but affect both men & women emotionally"; "Most men wait too long and endure pain too long before seeking help. Prostate problems may ultimately kill them or simply make them impotent for the rest of their lives."; "In both France and Italy, extract of Pygeum is recognized for prostate therapy and is available by prescription. Pygeum is the preferred method for treating prostate disorders ranking above surgery. Younger men are more likely to suffer prostate infections than BPH. Pygeum is a natural antibiotic, and is ideal for treating the infection."; "Chronic prostatitis, where inflammation of the gland is combined with infection, has been found to respond to treatment with zinc."; "Do you ... get up at night to urinate? ... often have sudden urges to urinate? ... have a weak urine stream? ... frequently need to urinate? ... have the sensation that you have not emptied your bladder completely after urinating? ... stop and start again several times when you urinate? ... have to push or strain to begin to urinate?" and
 - o "Arthron": "Arthron is more effective in treating arthritis, because it reduces pain, swollen joints, and stiffness"; "As an alternative treatment to arthritis pain, there is a powerful blend of natural ingredients which have been used to treat bone and joint diseases. These ingredients ... supply 100% natural relief for "Deep in the joints" aches and pains due to arthritis. They also reduce joint inflammation and stiffness, helping to provide you with greater freedom of movement. Even long term sufferers will receive relief. No more sleepless nights and painful annoying days. This 100% natural relief preparation is called "Arthron" and is now available, for the first time, to the public."; "Arthron ... helps your body fight the aches and pains of arthritis without the side effects of aspirin, ibuprophen[sic], or cortisone."; "Boswellin: an alternative to NSAIDS. It has been shown to reduce pain, swollen joints and morning stiffness. Also improves grip and physical performance."; "Bromelain: another powerful anti-inflammatory ingredient"
 - o "VitaOptics": "Begin protecting your eyes today! glaucoma; diabetic retinopathy; macular degeneration; cataract"; "Recent studies confirm that vision degeneration,

especially when detected early, may be stopped, and frequently may even be reversed, with the use of antioxidant supplements."; "VitaOptics significantly helps ... reduce risk of cataracts, masular[sic] degeneration and glaucoma; control sever nearsightedness"; "VitaOptics with Bilberry is a special blend of antioxidant vitamin and mineral supplements, which may significantly stabilize visual sharpness and contrast sensitivity in people that are beginning to or are already suffering from vision loss. Scientific controlled studies have found that antioxidant formulas are associated with reduced risk for cataracts and macular degeneration. These two diseases are the leading causes of blindness in the U.S."; "VitaOptics is a nutritional supplement developed for people suffering from eye problems and for people who want to plan ahead and possibly avoid these problems."

Based on the claims made for these products, these products are drugs [Section 201(g) of the Food, Drug, and Cosmetics Act (the Act)]. They are also new drugs [Section 201(p) of the Act] and may not be legally marketed in the United States without approved New Drug Applications (§505).

These drugs are also misbranded [§ 502(f)(1)] because the labeling fails to bear adequate directions for use and the labeling is false and misleading as it suggests that the products are safe and effective for their intended uses when this has not been established [502(a)].

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

We note that you market additional products also promoted with disease claims. Examples include:

- o "S-C-B": "Deadly arterial plaque (fat deposits) may be building up in your arteries right now! Because of this buildup you may be vulnerable to heart attack, stroke, or arteriosclerosis. But there is good news. There is help available, you may be able to clear clogged arteries, may be able to lower your cholesterol

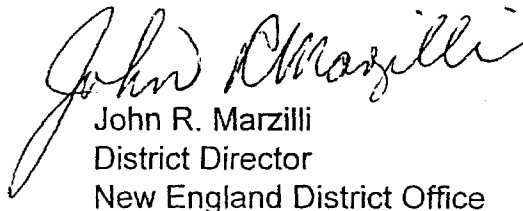
level and you may be able to live longer with a better quality of life ... All this is possible thanks to Formula S-C-B."; "The recent discovery of a new, all natural artery cleaner may turn into the major health breakthrough we've been hoping for."; "This amazing, 100% natural tablet reduces fatty build-up in the blood vessels ... so there's much less change[sic] of atherosclerosis or diet-induced heart trouble."; "It has actually cleared clogged arteries in some people."; "It has dramatically cut cholesterol in almost everyone who has taken it - even when cholesterol-lowering pharmaceuticals failed".

- o "C+G Sulfates": "Reverse your arthritis/Repair damaged cartilage/Reduce inflammation!"; "we're willing to bet, more than anything, you'd like to be free of the pain and restrictions arthritis forces upon you."; "There are numerous types of arthritic conditions, the three most common known forms of the disease are: Osteoarthritis is a degenerative disease of the large weight-bearing joints ... Rheumatoid arthritis is an autoimmune disease that incapacitates the synovial tissue ... Gout is a type of arthritis in which the level of uric acid ... "; "In Europe, some doctors have routinely been using these materials to treat arthritis since the early 1980's."

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, New England District Office; Attention: Bruce R. Ota, Compliance Officer.

Sincerely,


John R. Marzilli
District Director
New England District Office